

Application No.: 10/666,477

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c.) Remarks

As of this response, claims 1-15 remain pending.

Outstanding Rejections/Objections

The Examiner has entered the following rejections:

1. Claims 1-2 are rejected under 35 USC § 102(b), as being anticipated by U.S. Patent 4,281,420 to Raab ("Raab '420").
2. Claims 7-8, 11, and 14-15 are rejected under 35 USC § 102(e) as being anticipated by U.S. Patent 6,290,726 to Pope et. al. ("Pope '726").
3. Claims 1-7 and 11-13 are rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent 5,674,293 to Armini et. al. ("Armini '293") in view of Raab '420.
4. Claims 9-10 are rejected under 35 USC § 103(a) as being unpatentable over Armini '293.

Applicants address each rejection in turn.

1. Rejection of Claims 1-2 under 35 USC § 102(b)

The examiner has rejected claims 1-2 under 35 USC § 102(b), as being anticipated by Raab '420. Applicants respectfully traverse the rejection.

In the portions of Raab '420 cited by the examiner, the reference does not teach or disclose a prosthesis comprising a bearing surface comprised of an abrasion resistant surface (as that term is defined in the instant specification; see e.g., paragraph [0020]) cooperating against a counter-bearing surface comprising cross-linked polyethylene. For that matter, applicants could not find such a disclosure anywhere in Raab '420. Raab '420 is concerned with the fixation

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surface of the prosthetic device and not the bearing surface of the device. In contrast, the instant claims are concerned with bearing surfaces. The fixation surface is that surface that attaches to the host bone and immobilizes the prosthetic device in place. The bearing surface is that surface which bears the weight of the implant recipient after implantation. Referring to Figure 1 of Raab '420, the fixation surfaces are shown as "3" and "6". Although the bearing surface of Raab '420 is not labeled by a numeral, it is the surface of the femoral head and the inside surface of the acetabular cup "4" which contacts the femoral head. (It is likely not labeled because the discussion in the specification is not concerned with it). Nowhere is Raab '420 concerned with this bearing surface. Raab '420 is concerned with removing weak boundary layers on the fixation surface and one way this may be accomplished, according to Raab '420, is by cross-linking (see Raab '420 at col. 4, ll. 34-44). For example, at col. 6, ll. 60, Raab '420 is discussing the mechanical strength of the bond (i.e., fixation) and not the bearing surface. Also in example 6 of Raab '420, the specification discusses shear strength which is the fixation strength of the implant.

None of the teachings of Raab '420 discloses a prosthesis comprising a bearing surface comprised of an abrasion resistant surface cooperating against a counter-bearing surface comprising cross-linked polyethylene. There is no mention of an abrasion resistant surface in Raab '420 because Raab '420 does not discuss bearing surfaces anywhere. Raab '420 is not concerned with bearing surfaces. Raab '420 only discusses fixation surfaces because the purpose of Raab '420 is the improvement of implant fixation. Accordingly, Raab '420 does not teach an abrasion resistant surface cooperating with cross-linked polyethylene at a bearing surface interface. Raab '420 is concerned with fixation of the prosthesis in the bone cavity, not with the articulation of part of the prosthesis with either another part of the prosthesis or with tissue. The

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teachings of Raab '420 are focused on the use of PMMA on surfaces in which weak boundary layers, such as contaminants and weak oxide layers, have been removed. Cross-linking of polyethylene is discussed in Raab '420 at col. 6, ll. 34-44, but only in the context of the removal of weak boundary layers, which, as Raab '420 points out throughout its entire specification, is a problem in fixation surfaces. Raab '420 is concerned with fixation of prostheses in the bone implant site, while the present claims are concerned with maximizing the performance of the articulating surfaces (i.e., the bearing surfaces) of prosthetic implants by minimizing wear. It is not surprising, then, that Raab '420 does not teach a prosthesis having a bearing surface on the prosthesis body comprised of an abrasion resistant surface and a counter-bearing surface comprising cross-linked polyethylene and adapted to cooperate with the bearing surface.

In light of the arguments provided, applicants respectfully request that the examiner withdraw the rejection of claims 1-2 under 35 USC § 102(b) over Raab '420.

2. Rejection of Claims 7-8, 11, and 14-15 under 35 USC § 102(e)

The examiner has rejected claims 7-8, 11, and 14-15 under 35 § 102(e) as being anticipated by Pope '726. Applicants respectfully traverse the rejection.

The invention of Pope '726 is a diamond-on-diamond bearing surface. Nowhere does Pope '726 teach or disclose a prosthesis having at least one surface of blue-black or black oxidized zirconium. As discussed at length in the specification, the blue-black or black oxidized zirconium surface of the instant claims is a specific oxide composition that is distinct from passive oxides that form spontaneously in the presence of oxygen. The blue-black or black oxidized zirconium of the instant claims is formed only under certain conditions. The blue-black or black oxidized zirconium of the instant claims is discussed in the instant specification, *inter*

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alia, at paragraphs [0056] to [0059]. Nowhere does Pope '726 teach or disclose a prosthesis having at least one surface of blue-black or black oxidized zirconium.

Additionally, nowhere does Pope '726 teach or disclose a prosthesis having at least one surface of blue-black or black oxidized zirconium contacting at least one surface of cross-linked polyethylene. In fact, Pope '726 teaches away from the use of cross-linked polyethylene. At the portion of the specification cited by the examiner (col. 4, ll. 42-53), Pope '726 teaches that cross-linking of polyethylene has "unanticipated effects" (col. 4, ll. 44) and has "deleterious effects" (col. 4, ll. 50). Pope '726 criticizes the use of cross-linked polyethylene and teaches that a diamond-on-diamond bearing surface is superior. Pope '726 is fairly interpreted by one of ordinary skill in the art as teaching away from the use of cross-linking for prosthetic implants.

Thus, the teachings of Pope '726 contrast sharply with the invention of the instant claims. In the instant invention, the inventors teach minimizing any potential problems with cross-linked polyethylene by using a counter-bearing surface of blue-black or black oxidized zirconium (or other abrasion-resistant surface) against it. Pope '726, on the other hand, suggests elimination of cross-linked polyethylene altogether.

Thus, Pope '726 fails to teach or suggest a prosthesis with at least one surface of blue-black or black oxidized zirconium. Additionally, Pope '726 fairly teaches away from the use of cross-linked polyethylene for bearing surfaces of prosthetic devices. In light of the arguments provided, applicants respectfully request that the examiner withdraw the rejection of claims 7-8, 11, and 14-15 under 35 USC § 102(e) over Pope '726.

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3. Rejection of Claims 1-7, and 11-13 under 35 USC § 103(a)

The examiner has rejected claims 1-7, and 11-13 under 35 § 103(a) as being unpatentable over Armini '293 in view of Raab '420. The examiner asserts that Armini '293 discloses all elements of the instant claims except that of the at least one surface of cross-linked polyethylene. The examiner then asserts that one of ordinary skill in the art would use the teachings of Raab '420 to supply the teaching of at least one surface of cross-linked polyethylene. Applicants respectfully traverse the rejection.

As discussed at length above, Raab '420 is not concerned with bearing surfaces, and does not teach a prosthesis having a bearing surface on the prosthesis body comprised of an abrasion resistant surface, and a counter-bearing surface comprising cross-linked polyethylene. Applicants refer to their comments in section 1 above. While it does mention UHMWPE and cross-linking at col. 6, ll. 34-44, it does not do so in the context of a bearing surface. Raab '420 is concerned with fixation (non-bearing) surfaces only.

Nowhere does Armini '293 teach or disclose a prosthesis having a bearing surface on the prosthesis body comprised of an abrasion resistant surface and a counter-bearing surface comprising cross-linked polyethylene and adapted to cooperate with the bearing surface. Accordingly, the combination of Armini '293 with Raab '420 still lacks a teaching of an abrasion resistant bearing surface and a counter-bearing surface comprising cross-linked polyethylene. As discussed in applicants response to the first rejection in the outstanding office action, Raab '420 similarly fails to teach a prosthesis having at least one surface of blue-black or black oxidized zirconium or a prosthesis having a bearing surface on the prosthesis body comprised of an abrasion resistant surface and a counter-bearing surface comprising cross-linked polyethylene and adapted to cooperate with the bearing surface. Because of this deficiency in both Armini

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'293 and Raab '420, neither reference taken alone, nor their combination, renders the instant claims unpatentable under 35 USC § 103(a).

In light of the arguments provided, applicants respectfully request that the examiner withdraw the rejection of claims 1-7, and 11-13 under 35 USC § 103(a) over Armini '293 in view of Raab '420.

4. Rejection of Claims 9-10 under 35 USC § 103(a)

The examiner has rejected claims 9-10 under 35 § 103(a) as being unpatentable over Armini '293. The examiner asserts that Armini '293 discloses all elements of the instant claims except that of a surface of blue-black or black oxidized zirconium of between 1 and 20 microns. The examiner notes that "where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. Applicants respectfully traverse the rejection.

This rejection is incorrectly based on the assumption that Armini '293 discloses a prosthesis having a bearing surface on the prosthesis body comprised of an abrasion resistant surface and a counter-bearing surface comprising cross-linked polyethylene and adapted to cooperate with the bearing surface. Armini '293 neither teaches nor suggests this. As applicants have discussed above, because Armini '293, either taken alone or in combination with any other cited reference, is not competent to render parent claim (i.e., claim 7) of claims 9 and 10 unpatentable, Armini '293 is similarly not competent to render claims 9 and 10 unpatentable.

In light of the arguments provided, applicants respectfully request that the examiner withdraw the rejection of claims 9-10 under 35 USC § 103(a) over Armini '293.

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d.) Conclusions

In light of the arguments made herein, Applicants respectfully assert that the pending claims are in condition for allowance. Because the Examiner's rejections have been addressed, Applicants respectfully request withdrawal of the outstanding rejections. Accordingly, Applicants earnestly request allowance of the application. This is intended to be a complete response. If any issues remain outstanding, please contact the undersigned for resolution of the same.

Applicants believe that no fees are due or associated with the filing of this document. However, if Applicants are in error, the Commissioner is hereby authorized to draw any additional fees associated with this filing from Deposit Account No. 06-2375, under Order No. P02228US1/10105654, from which the undersigned is authorized to draw.

Respectfully submitted,

Date: December 8, 2005

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